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(71)(72) Applicants and Inventors: WESTENSKOW, Dwayne [US/US]; 3439 Winesap Rd., Salt Lake City, UT 84121 (US). ORR, Joseph [US/US]; 1219 University Village, Salt Lake City, UT 84108 (US).

(74) Agent: NORTH, Vaughn, W.; 9035 South 700 East, Suite 200, Sandy, UT 84070 (US).

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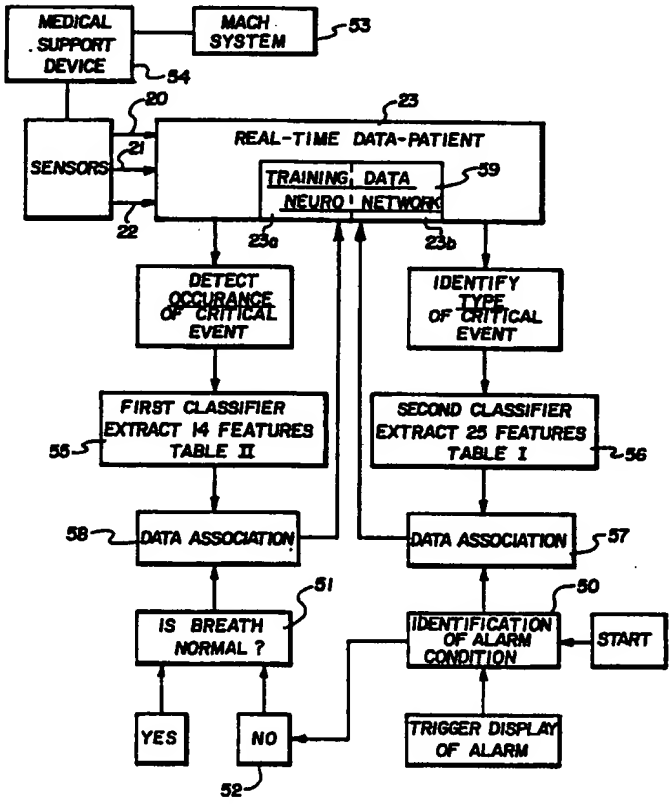
(54) Title: DEVICE AND METHOD FOR NEURAL NETWORK BREATHING ALARM

(57) Abstract

A method involving the supply of data (20) to input nodes (24a-e) of a neural network with respect to the breathing function. Alarm conditions of critical events are identified and associated with coordinated images generated at the output of the neural network (29m-q) as the system is trained. In such training, the neural network and associated system are subjected to the alarm condition to produce the desired coordinated image. This coordinated image is correlated with an alarm activating signal and the specific alarm condition to which it is to be identified in connection with future comparisons. During subsequent use in clinical applications, the monitoring system, (23, 50-52, 55-59, 63-68 and 70-71) screens data generated for each breath and compares the corresponding coordinated image with previous images generated during training sessions for alarm conditions to be monitored. Upon occurrence of a similar image, the system signals and alarm (71) and identifies the cause for the critical event.



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DEVICE AND METHOD FOR NEURAL NETWORK BREATHING ALARM

The present invention relates to devices and methods for detecting abnormal conditions with respect to patients having attached medical support or diagnostic devices for ventilating the human body. More particularly, the present invention relates to a device and method for detecting and identifying alarm conditions associated with the delivery of anesthesia to a patient or to a patient's breathing circuit.

Each year about two to five thousand anesthesia related deaths occur in the United States. A primary factor in more than half of these mishaps is human error on the part of the anesthesiologist. More than half of these deaths could be prevented with improved anesthesia and integrated monitoring systems.

Current anesthesia monitoring devices each have their own display and alarm system. These typically comprise threshold alarms which trigger when a monitor parameter exceeds a preset, threshold level. Such levels are initially set by the user and must be reset during the procedure as the desired state of the patient changes. Therefore, current state of the art methods require the anesthesiologist to be involved in an on-going course of setting threshold levels for potential emergencies, and then monitoring for the

occurrence of such emergency conditions.

This environment is further complicated by the fact that recent studies show approximately 78% of all threshold alarms sounding because of spurious readings. Schaaf C: "Evaluation Of Alarm Sounds in the Operating Room," Proceedings Vail Conference, 1989. In short, the task of presetting alarms is so time consuming and the false alarms are so distracting that threshold alarms are generally disabled by the anesthesiologist. Kerr J. H.: "Warning Devices," Br J Anaesth 57: 696-708, 1985.

In general terms, critical conditions arising during mechanical ventilation of a patient fall within two categories. One set of events involves those occurrences which are physiological within the patient. These can often be detected by monitoring parameters within the breathing circuit; however, they may not be caused by mechanical ventilation per se. Other problems such as blocked air passages, leaking valves or hoses, sticking valves, disconnections or other mechanical failures of the system make up the second category of critical events. Typically, these occurrences can be immediately corrected if known. Unfortunately, the physical manifestation of physical or physiological and mechanical critical events are not always readily distinguishable. A decrease in oxygen uptake could be the result of a blocked passage or a leaking valve within the breathing circuit, or could be a consequence of physiological difficulties with the patient.

Many current alarm systems, if operational, serve to identify the occurrence of a critical event (i.e. decrease is oxygen uptake) but fail to give meaningful identification of the actual cause. The

anesthesiologist is therefore left to make threshold determinations of whether the cause is mechanical or physiological, and then make further assessments of probable cause within each of these respective categories. All of this must be done in an environment of great urgency and stress.

Specific alarm systems have been provided to assist anesthesiologists in this challenge. So called smart alarms have been developed to contribute to identification of the cause of a problem, as well as detection. The most common method of generating smart alarms is with a set of if-then threshold rules. For example, IF (1) the patient is mechanically ventilated, (2) expiratory title volume is less than 3/4 inspiratory title volume and (3) expiratory tidal volume decreased over 10% since the last measurement; THEN the patient is not getting full volume. THEREFORE, the smart alarm would suggest that the anesthesiologist check for a cuff leak. Although such alarms are a great improvement over traditional single parameter alarms, they suffer many of the same traditional problems. Noise causes many false alarms. In the above rule, a spurious tidal volume reading may cause a false alarm. Furthermore, rules based on thresholds are limited because the threshold levels must generally be predetermined as opposed to being set for individual cases.

Similarly, alarm rules can be established based on a model breathing circuit. Safe operational ranges may be identified, with alarms to be fired when measured parameters deviate outside this normal model. Here again, such alarms are based on generalizations as opposed to specific patient needs. Although this approach is an improvement, it requires many sensors to collect the necessary parameters for accurate

comparison with the model.

A second form of smart alarm system is commonly referred as an expert system. With an expert system, rules are applied in a collective rather than individual sense. In other words, many situations may be coordinated within an expert system, rather than depending only on a preprogrammed series of events, as is common with traditional smart systems. The expert system searches for and links together all the rules that apply in each specific situation.

Unfortunately, expert systems are inherently slow. They require large amounts of computer power to make decisions, and they are limited by weaknesses inherent in the rules themselves. Usually, these rules fail to make use of all of the information available. If-then rules are based on only one or two measured parameters; however, the collective sum of the subtle changes in other parameters which may not be covered by the rule may contain significant information. Such information may be essential to correctly report a critical event or identify its possible cause.

A further weakness of expert systems lies in the process of selecting threshold levels. Such threshold levels may represent maximum or minimum values on given parameters which must be arbitrarily fixed. Obviously, the assignment of such threshold values must be an estimation based on an individual's judgment. Although an experienced expert can surely reduce the error of deviation, the process is inherently flawed by the fact that some minimum or maximum value must be specifically fixed. In reality, the actual measured values will be affected by many parameters which frustrate even experts'

efforts in attempting to focus on specific ranges of acceptable measurement or performance.

All of the foregoing methods share a common focus. This is characterized by a traditional approach dependant upon sensors which function to detect readings occurring outside specified ranges. In other words, the detection of critical events, even with the use of artificial intelligence systems, has focused on assignment of a safe range of measurement coupled with signaling of an alarm condition upon the measurement exceeding such a range. Ongoing improvements within this arena have generally focused on enhancement of sensing devices to reduce tolerances and increase effectiveness of range determination. In other words, detection and identification of critical events in the medical environment, and particularly in administration of anesthesia and mechanical ventilation, have focused on assessment of component factors which collectively make up the total picture. Although the more sophisticated expert systems correlate the various component measurements, the emphasis remains on accurate sensing of each parameter and assignment within a safe range of operation.

An inherent by-product of this methodology is increased complexity in monitoring systems. For example, increasing knowledge requires increasing numbers of sensors to measure the growing number of parameters needing evaluation. To enhance accuracy of measurement, more complex sensors and monitoring equipment are applied. This not only generates increased costs but greater risks as sophistication of equipment increases. Obviously, such growing complexity directly affects the need for enhanced training and qualification of anesthesiologists and

attending personnel.

It is an object of the present invention to provide a device and method for detecting and identifying critical events or alarm conditions in a medical environment without the need of individually evaluating individual parameters, thereby leading to simplification rather than complication of the process.

A further object of the present invention is to provide a device and method for detecting critical events within a breathing circuit by monitoring sensor output as a whole in contrast to individual sensor readings and determination within ranges.

A still further object of the present invention is to detect and identify critical events within a breathing circuit by identifying a composite measurement of numerous individual parameters which make up a total picture of the patient's environment.

An additional object of the present invention is to provide a device and method for detecting and identifying critical events which relieve the anesthesiologist of much of the evaluation effort by both detecting and identifying the cause of a given problem.

A further object of the present invention is to provide a diagnostic approach within the field of ventilation assistance which can be both self-training and self-correcting while reducing both complexity and cost.

These and other objects are realized in a device and method which may operate in real time

environment within a mach set up, test animal or patient and with respect to a test medical support or diagnostic devices. This method comprises the steps of identifying at least one physiological function to be monitored with medical support or diagnostic devices and identifying a plurality of features within data to be generated by such support or diagnostic devices during operation. These diagnostic devices are attached to the mach set up, test animal or patient and are operated to generate data representing the various identified features to be monitored. This data is inputted into input nodes of a neural network capable of generating a single coordinated image for the combined input data. At least one alarm condition associated with the physiological function or device attached is identified. This identification serves to program a system for future detection of the stated alarm condition. The alarm condition is then empirically created within the mach set up or is observed and measured within the test animal or actual patient while such data is being inputted to the input nodes of the neural network. Accordingly, this data representing the identified features produces a single picture or coordinated image which corresponds to the alarm condition to be detected in the future. This coordinated image is correlated within an associated alarm activating signal in memory for future recall on comparison. Upon re-occurrence of a similar coordinated image at the input nodes of the neural network, the alarm signal automatically activates and identifies the pre-determined or trained condition corresponding to that coordinated image. This system allows the monitoring equipment to compare the total picture provided by input data with a library of pre-determined pictures which were generated empirically and assigned to certain critical events. Upon identification of a similar picture, the monitoring

system is able to both detect and identify the problem and cause with surprising accuracy.

Other objects and features of the present invention will be apparent to those skilled in the art, based on the following detailed description in combination with the accompanying drawings.

In the drawings:

Figure 1 shows a graphic representation of a breathing circuit typically applied in mechanical ventilation of a patient.

Figure 2 shows a graphic representation of a neural network in accordance with the present invention.

Figure 3 graphically illustrates the operation of a neuron within the neural network of Figure 2, including the related summation equation.

Figure 4 is a graph of a decision boundary based on a single layer of neurons.

Figure 5 is a graph of a neural network decision boundary having two layers as input and output respectively for defining linear boundary edges.

Figure 6 graphically illustrates an actual boundary generated by increasing the number of neurons in each layer to provide boundaries defined by secondary equations.

Figure 7 is a graph illustrating exclusive -- or boundary areas generated by a neural network

having an intermediate layer of neurons as illustrated in Figure 3.

Figure 8 depicts a block diagram of the general procedure of the present invention as applied to training a neural network to recognize specific critical medical events.

Figure 9 provides a block diagram illustration of the present invention for purposes of applying the trained data network to detect and identify actual critical events with relation to an actual patient.

Referring now to the drawings:

Figure 1 illustrates a patient breathing system in a process of mechanical ventilation such as would be used in the administration of anesthesia to a patient. The system includes a ventilator 10 coupled to an inspiratory valve 11 and through an inspiratory hose 12 to a pneumotach 13. The patient is coupled via an endotracheal tube 14. The expiratory circuit extends from the hose 15 through an expiratory valve 16 and CO_2 absorption canister 17. Actual operation of this system is well known to those skilled in the art and needs no further explanation.

The patient breathing system shown in Figure 1 is intended to generally represent any system for mechanical ventilation of a patient. This may be a support system or an anesthesia delivery device. More generally, the illustrated breathing system is intended to represent medical support or diagnostic devices which are generally used to monitor physiological functions of the patient. In the present case, the physiological function being

monitored is breathing. It is envisioned, however, that the concepts to be discussed hereafter may be applied to other unrelated medical areas such as cardiac support and diagnostic systems wherein the physiological function being monitored is the heart and circulatory system. These are, of course, considered exemplary and not limiting.

The present invention involves a method for detecting and identifying abnormal conditions in a realtime environment. These conditions may occur within a mach setup such as an oil/water lung model or other similar mach systems where multiple inputs of data may be applied to represent a given condition of the medical support or diagnostic device. More importantly, this method can be applied to a test animal or a patient with attached medical support or diagnostic devices to monitor conditions which may constitute critical events or abnormal circumstances requiring immediate medical attention.

Such conditions are typically identified by monitoring certain features representing data output from the medical support or diagnostic device during operation. For example, the system of Figure 1 is fitted with three sensors which respectively monitor different features of the physiological function of breathing. The CO_2 sensor 20 provides ongoing measurement of the feature of CO_2 concentration in the inspired and expired air. In the present instance, these measurements are taken by a Nihon Kohden (Model OIR) infrared CO_2 sensor; however, other sensor devices may be equally suitable. An additional feature is airway pressure. This is monitored by a Sensym (SCXOIDN) transducer represented in block diagram as a pressure sensor 21. A third feature of the breathing function to be monitored by the present

invention is gas flow rates as measured by a Fleisch #0 Pneumotach coupled to a differential pressure sensor 22 comprising a Validyne (MP 45-22) pressure transducer 22. Additional sensors and diagnostic devices may be applied within the breathing circuit; however, actual use of this system has confirmed the adequacy of monitoring these primary features of the breathing function.

The analog signals from the three transducers are sampled at 60 hertz with 12 bit resolution by a Zenith 386 computer 23 or some other form of computerized data controlled system which receives input data from 20, 21 and 22. These three primary features are broken into component features which have been classified into two categories. The first category comprises 25 features selected for their high information content. These features are set forth in the following Table I.

TABLE I

DIFFERENTIAL FEATURES

Expired O_2, CO_2 and Anesthetic Agent Curves

1. upstroke slope
2. downstroke slope
3. phase III slope
4. phase I time
5. phase III time
6. minimum value
7. F_{ET} (end-tidal)
8. variance of phase III
9. number of oscillations in phase III/phase III time
10. I:E ratio

Flow - Volume Curve

11. start volume - end volume
12. peak inspiratory flow
13. peak expiratory flow
14. mean expiratory flow
15. rise volume
16. volume at peak expiratory flow
17. respiratory rate

Pressure - Volume Curve

18. inspiratory tidal volume
19. expiratory flow variance
20. number of flow loops/tidal volume
21. pressure volume slope
22. end pressure - starting pressure
23. peak airway pressure
24. minimum airway pressure
25. area

These features are selected from the flow-volume curve, pressure-volume curve and from the CO_2 wave form generated by the respective sensors. As will be explained in greater detail hereafter, these 25 differential features are used by the present invention to identify the actual critical event which has occurred to cause a change in the patient breathing. This is in contrast to mere detection of the critical event.

Detection of the event is accomplished by a second category of features identified in Table II.

TABLE II

ABSOLUTE FEATURES

1. CO_2 upstroke slope
2. CO_2 downstroke slope
3. CO_2 plateau slope
4. (phase I volume - phase III volume)/inspired tidal volume
5. $(F_{ET}\ CO_2 - F_I\ CO_2)/F_{ET}\ CO_2$
6. number of phase III oscillations/phase III time
7. (inspired volume - expired volume)/inspired volume
8. (mean inspiratory flow - peak expiratory flow)/mean inspiratory flow
9. rise volume/inspiratory tidal volume
10. volume at peak expiratory flow/expiratory tidal volume
11. expiratory flow variance
12. slope of pressure volume curve
13. ending pressure - starting pressure
14. area of pressure volume curve

These 14 absolute features are used to determine if a breath is normal. This determination is made with each breath independently. No specific comparison is

made with preceding or successive breaths to assess whether the breath falls within an abnormal classification. If the breath is normal, no alarm display is triggered. If an abnormal breath is detected, a data comparison between realtime data input through the neural network for the selected 25 features is made with "trained" data previously developed and recorded in computer memory. Identification of the critical event is determined by association between trained data and on-line data and an appropriate alarm is displayed.

This two layer approach results in absolute features (exemplified by the 14 features of Table II) which are more or less independent of patient size and breathing system configuration. The differential features (Table I) are more or less independent of breathing mode, gas concentration and abnormal physiology. These 25 features are taken into account upon occurrence or identification of the abnormal breath.

A neural network as is illustrated in Figure 2 provides the mechanism for determining the occurrence of the abnormal conditions or critical events to be monitored. The neural network is a mathematical model similar to neural cells which are linked together to create a network which can be taught or trained to identify sets of inputs which appear to be similar to the example input sets previously supplied to the network in a training situation. The system learns to recognize critical events by seeing the events as represented by input data at the neural network during such a training session.

Each cell or neuron 25 has an input side and an output side as illustrated in Figure 3. The input

side receives multiple signals while the output comprises a single signal.

The form of neural network applied in the present invention is a Backward Error Propagation system and is well known to those skilled in the art. Its basic building block is the neuron 30, corresponding to the cells or neurons 25 in Figure 2. Input data registers as X_0 through X_N. With this input data, a single output signal Y is generated. The neuron 30 separates data into two classes using a linear decision boundary 31 as shown in Figure 4. Data mapped onto one side of the boundary are mapped as belonging to one group (i.e. group A) and data mapped to the other side are classified as belonging to the other group (group B).

The enclosed boundary condition provided in Figure 5 is a product of including four neuron cells in adjacent configuration and by interlinking all of their outputs, as is illustrated in Figure 2. For example, input level 24 registers five input sources a, b, c, d and e. These represent sources of input data. For example, when reading differential features from Table I, input data at "a" would correspond to the upstroke slope of the gas curves. Input "b" would correspond to the downstroke slope, "c" to the phase III slope etc. These data signals are then interlinked with the first layer of neurons 25 by interlinking connections 28.

Specifically, input 24 "a" has seven connections each tied respectively to neurons f, g, h, i, j, k and l. Input from b similarly is interlinked to each respective neuron f through l. Therefore, neuron f in layer 25 generates an output signal based on the cumulative effect of the five input signals

received from inputs a through e. In this manner, the parallel influence of input data registered from a, b, c, d and e is concurrently sensed at each of the respective neurons f through l, the five inputs shown in the example of Figure 2 would generate a five dimensional graphic with a closed boundary of at least seven sides based on seven neurons at level 25, in contrast to the four sides illustrated in Figure 5. More complex decision boundaries such as those shown in Figure 6 can be generated with more complex neurons configured in multilevels. Such examples are shown in Figures 6 and 7.

The graphic illustration in Figure 7 shows an exclusive-- or boundary condition wherein groups 35 are exclusively separated by members of the second group B. This separated boundary condition is accomplished by utilizing a third layer of neurons. This third layer allows data to be classified into a particular class if data points are located in one region or if they are located in a separate region of the feature space such as areas 36 and 37.

Although each neuron in level 25 receives the same signals "a" through "e", the respective neurons are trained to assign different weights of significance to input data received. This technique of weithting input values is also well known to those skilled in the art. For example, neuron "f" receives input from a through "e" but may not give equal value to each input. Input from "a" may be determined more significant for a particular critical event than input from "d". By differentiating or weighting the respective inputs from "a" through "e" at each of the neurons "f" through "l", thousands of combinations or rules can be generated which relate input from the transducers as a whole to the output of the neural

network at neurons m, n, o, p and q. These techniques can be applied to differentiate or weight the input not only from level 24 (a through e) to level 25 (f through l), but also from level 25 to level 29 "m" through "q". In other words, each of the respective inputs from neurons "f" through "l" are weighted to generate a variety of values for neurons "m" through "q".

Programming of these respective neurons with differential weighting factors may be accomplished by numerous state of the art techniques. One common technique is that of backward error propagation. Techniques are disclosed in Rumelhard D. E., Hinton G. E., Williams, R. J., "Learning Internal Representations by Air Propagation". In Rumelhard D. E., McClelland, J. L. (eds): Parallel Distributed Processing, Cambridge, Mass. MIT Press, 1988. Conventional algorithms are available to process these steps and generate outputs of a unique pattern for each separate set of inputs and their included weighting factors.

A neural network such as that illustrated in Figure 2 is implemented in the present invention with respect to the physiological function of breathing by using input data identified in Tables I and II. Each of these data items is considered to be a feature monitored by the medical support or diagnostic device during operation.

The neural network operates within the subject breathing apparatus in a manner similar to the human brain. It learns by experience to associate certain combinations of input data received from many sources with a certain type of emergency condition or critical event. Initially, the neural network must be taught to associate the critical event with data input. This

is accomplished by attaching the medical support or diagnostic such as the mechanical ventilating system of Figure 1 to a mach setup, test animal or patient. This system is then set in operation to generate data representing the identified features (Table I or Table II). This data enters through a set of neural network inputs at level 24, elements "a" through "e". As previously indicated, each of these data inputs is identified as a feature, such as the slope of a curve, volume of flow measurement, pressure measurements or other data forms which are extracted from the transducers 20, 21 and 22. The neural network receives this data at its input nodes a, b, c, d and e and networks its signals to all of the neurons at the next level 25 (f-1).

With the device in operation and data being generated to the neural network, the operator identifies an alarm condition or critical event which is to be associated with the physiological functions or medical support/diagnostic device which is to be programmed for detection. For example, Table III lists 14 conditions which are considered critical events requiring immediate attention.

TABLE III

Critical Events

1. ET tube obstruction
2. ET tube Leak
3. ET disconnect
4. insp. hose obstruction
5. insp. hose leak
6. exp. hose obstruction
7. exp. hose leak
8. insp. valve leak
9. insp. valve stuck
10. exp. valve leak
11. exp. valve stuck
12. no alarm
13. insp. hose disconnection
14. exp. hose disconnection

One of these critical events is selected and identified as an alarm condition for detection. This condition is then empirically created or measured within the mach setup, clinical test animal or actual patient such that the input data being inputted to the input nodes 24 (a through e) produce a coordinated image at output nodes 27 which correspond to the alarm condition. For example, if the identified condition is an obstruction in the endotracheal tube as identified by item 1 in Table III, and the device is attached to a mach setup, the tube would be obstructed and data would be introduced at the input side 24. The algorithm would then train the neural network memory with respect to the identified condition which would be represented by the coordinated image or output signal produced by the combined output of neurons m through q. This coordinated image unique to the alarm condition would be associated with an alarm activating signal which is stored in the computer's memory for future recall and comparison. In the event the neural network recognizes this same coordinated image at the output, the computer would automatically generate the alarm activating signal. This signal would identify not only the occurrence of a critical event, but would in fact identify the specific event based on the ability of a neural network to associate and recall that information which it was formerly trained. In essence, the coordinated image representing the data output 27 is analogous to a snapshot at a given point in time reflecting all of the inner relationships and weighting factors assigned to the input data. Rather than attempting to detect the occurrence or identify the cause of a particular critical event by isolating any of the 14 or 25 specific features, the neural network assimilates all the information in parallel as opposed to serial form and merely looks for that coordinated training image

which most resembles the actual reading taken on-line with the patient.

In the specific adaptation of the present invention to a patient breathing system, two goals are accomplished. First, the present invention monitors critical events to detect its occurrence. This may be accomplished as a threshold consideration which must arise or it may be accomplished concurrently with the second object of identifying the specific critical event or cause. Ideally, these separate classifications are implemented with two separate neural networks, each having a separate set of inputs. The systems may then operate to detect events independently or in concert. Each of the two classifiers uses input data derived from the same monitored physiological signals; however, these signals supply different types of information or features to accomplish different objectives.

For example, the input to the first classifier are totally concerned with the current signal in its absolute form. For example, the first feature identified in Table II provides data on CO_2 upstroke slope. Each time the patient takes a breath, a new set of signals are generated which are independent from signals generated by both the previous and subsequent breaths. Specifically, the first classifier network does not compare the absolute value of the new data being received with previous data. It merely looks at the value of the slope in absolute frame of reference and classifies that value as normal or abnormal. As long as the classification is normal, the network registers no signal or may have a specific output mode biased in the on position, corresponding to a normal breath. If an abnormal breath occurs, the 14 absolute features of Table II respond with a

corresponding coordinated image is generated for that single breath, triggering the appropriate alarm sequence.

An advantage of including an absolute classifier is the ability of the device to detect events whose effect on the monitored signal occurs slowly, over a significant duration of time. For example, it is important to be able to detect alarm conditions which are present at the immediate commencement of medical procedures. Furthermore, the device must have the ability to prevent false alarms due to adjustments in the monitored system as may be developed by the patient, the physician or by attendant circumstances. Without this absolute classifier, an event causing very gradual changes may go undetected. Conversely, if an anesthesiologist must make an adjustment in patent ventilation, a system of differential classification would see the adjustment as a critical event, again sounding the alarm.

The value of the present invention is that it provides a two level classification system which first registers the occurrence of an event based on absolute values, but also evaluates changes in conditions during the course of system operation. Without this second classifier capability, the system would lack specificity because of differences between patients. An absolute value for one patient may not be indicative of an absolute value for another. Similarly, a physiologic signal corresponding to one type of critical event for one patient may be easily confused with that of another event for a different patient. This confusion makes the absolute classifier inadequate for determining the specific type of critical event which may have occurred.

Therefore, the present system embodies a second classifier which compares a current coordinated image with previous coordinated images of earlier readings. This personalizes the monitoring to the specific patient by allowing the neural network to develop an historical record for the various differential features identified in Table I. The strength of this differential classifier is its ability to identify specific events in spite of interpatient differences. This is because the difference between a monitored signal in Table I from a previous signal has less patient-to-patient variation than do the absolute signal values of Table II. Therefore, the differential classifier has greater specificity.

The weakness of the differential classifier is that it fails to detect a critical event if the event changes very slowly over time. Also, the differential classifier fails to detect an event if the classifier system starts during the occurrence of the critical event or alarm situation. As implied earlier, the differential classifier also would respond to variations caused by adjustment of the system by the anesthesiologist. This is so because the classifier sees only the change and ignores the fact that the monitored signal, both before the system adjustment and after the adjustment, were both normal and acceptable.

Therefore, by including both absolute and differential comparisons within the neural network program, the generated coordinated images are subject to both absolute evaluation and comparative evaluation. This greatly enhances the ability of the system to give full protection to the patient by optimizing the ability of the attending physician to detect and correct both absolute changes and those

which are a function of time.

With respect to actual alarm output, the present invention can be trained to recognize the reoccurrence of an earlier coordinated image which was assigned a given alarm condition. Therefore, the 14 alarm conditions listed in Table III would be conditions which must be taught to the neural network and programmed for recall and comparison. This comparison need not be an identical coordinated image in that the signals could be superimposed, but could simply be that coordinated image and memory which is most similar to the newly detected image. Accordingly, upon occurrence of an absolute feature characteristic of problems with the breathing system, the neural network would automatically compare the present coordinated image with its prior experience generated during teaching incidents. It would then identify the closest or most similar coordinated image and register the associated alarm signal.

In the present invention, this alarm signal is generally an audible warning indicating the need for immediate attention and corrective action. Concurrent with this warning is the designation of any component of the medical support or diagnostic device which is now functioning. The system is adapted to generate a graphic display on a computer screen showing medical support or diagnostic device with an identifier element designating the component which the neural network has identified as the possible malfunctioning element. Similar warning sequences may be applied to other critical events and causes as well.

These features are generally represented in a training application by the following steps.

Step 1: The specific physiological function (such as breathing) which is to be monitored with a particular medical support or diagnostic device should be identified. In the preferred embodiment, the medical support device comprises the anesthesia delivery system as represented in Figure 1. The physiological function is breathing. The present invention is applied by using the medical support device comprises the anesthesia delivery system as represented in Figure 1. The physiological function is breathing. The present invention is applied by using the medical support or diagnostic device as the data source to a neural network to monitor the breathing function.

Step 2: Several separate but related data characteristics or "features" which are generated by the medical support device must be identified which are indicative of the breathing function. Such features may be differential in nature such as the various air flow, volume and pressure data set forth in Table I or may be absolute features as described in Table II. In any event, these features are selected because of their utility in identifying changes or problems with respect to the breathing function.

Step 3: With the medical support device attached to a patient, test animal or mach set-up, and adapted with the means for generating the desired data including the identified features to be evaluated, the system is set into operation and data is generated representing the plurality of features.

Step 4: Generated data corresponding to each of the selected features is concurrently transmitted and inputted to input nodes of the neural network provided by a computer and an operating algorithm

which is capable of generating a single coordinated output "image" or signal for the combined input data. In other words, the incoming data representing (i) 25 different features for differential comparison or (ii) 14 absolute features is processed by the neural network to generate a single output signal which will represent an alarm condition to be detected during future use.

Step 5: The specific alarm condition (such as an obstructed endotracheal tube) is identified. Obviously, these have some relationship to the physilogical function or medical support or diagnostic device which is to be monitored. In the illustrated example previously described, 14 alarm conditions or critical events were identified and listed in Table III.

Step 6: In order to obtain data ouptut from the medical support device which is indicative of the alarm condition, one must create this condition within the mach set up, clinical test animal or actual patient in order to generated the type of data relevant to this condition. In other words, an intentional block is made in the endotracheal tube corresponding to critical event No. 1 in Table III. Incoming data to the neural network will correspond to the blocked tube and create the desired coordinated output or image which is to be recorded in the neural network memory. Accordingly, this step involves empirically creating the alarm condition such that the generated data concurrently inputted to the input nodes of the neural network will correctly represent and identify the created alarm condition.

Step 7: This data now needs to be labeled within the computer memory as representing the

specific alarm condition. To accomplish this, the single coordinated output signal or image generated by the neural network is correlated or associated with the identified alarm condition and a corresponding activating signal. These are all stored in the computer memory for future recall upon recurrence of a similar coordinated output signal.

Ideally, this method is applied in repetitive manner with respect to each alarm condition to generate a large statistical base of single output signals which serve as indicators of this alarm condition. This statistical gathering is made possible by identifying which features are most significant with respect to an identified alarm condition, and providing weighting factors with respect to those features to realize the single output for the neural network which corresponds to the alarm condition.

This is illustrated in the block diagram of Figure 8. The two respective functions previously described of (i) detecting the occurrence of a critical event and (ii) identifying the type of event are graphically set up in two columns in the figure. Ideally, two sets of neural network inputs 23a and 23b would be provided. Neural network 23a would have 14 inputs, corresponding to the 14 features identified in Table II. Neural network 23b would have 25 inputs, corresponding to the 25 features of Table I. As has been previously explained, the system would be trained by identification 50 of an alarm condition corresponding to one of the alarm conditions set forth in Table III (such as an obstructed endotracheal tube). By definition, the presence of an alarm condition will correspond to an abnormal breath 51 is identified with a negative response 52.

With the abnormal alarm condition defined, the amch system 53 is configured to simulate the alarm condition. For example, the endotracheal tube might be intentionally obstructed or clamped off so that the attached medical support device 54 and array of sensors 20, 21 and 22 submit data to the computer and neural network 23 corresponding to the simulated condition. This input data is evaluated by the neural network to develop a single coordinated data output or image for the Table II features 55 and Table I features 56. These respective coordinated output signals are manipulated by an appropriate algorithm for data association 57 and 58. This data association links the single coordinated ouptut signal representing Table I and Table II features, with the identification of alarm condition 50 and abnormalcy of breath 51/52. This combined data association is stored in the computer as training data 59. This data is used as part of a statistical collection of single coordinated output signals representing the given alarm condition. Future correlation of realtime data with the stored training data 59 is compared when the system is operated in a realtime detection mode (as contrasted with the training mode of Figure 8).

The detecting mode is depicted in Figure 9 by a similar arrangement of blocked diagrams, wherein the directional arrows for the lower two tiers of blocks are reversed. In the detection mode, a patient 60 has an attached endotracheal cuff and a supply line 61 which connects to a medical support device 62 in a manner similar to that illustrated in Figure 1. Sensor input is transmitted to the computer 23 for processing of input data 20, 21 and 22 and through the neural network. In the detection mode, the computer does not preassign any status of normalcy or abnormalcy to the incoming data. The data is

processed through the neural network by a computer evaluation of the identified 14 and 25 features represented in Tables II and I. As indicated in block diagram, these evaluations respectively will identify the "occurrence" of a critical event, and the "identity" thereof. The single coordinated output signal for Table II evaluations is represented by arrow 63. The single coordinated output signal for Table I features is similarly represented by arrow 64.

At this point, the data output 63 of Table II is compared with the training data 59 previously stored in the computer 23. The data association 65 compares data ouptut from the neural network 63 in the form of single coordinated output signals 59 which were previously created during the referenced training sequence. The computer 23 then detects whether the realtime output signal 63 correlates or is similar to any of the stored signals 59 representing an abnormal breath condition. If correlation is detected, the negative assessment 66 is registered and activates identification of the type of alarm condition 67 which may be causing the abnormal breath. In the absence of any correlation between the realtime signal 63 and the training data 59, the system is automatically programmed to respond with an affirmative status 68 of normalcy.

The identification of specific alarm conditions is accomplished by comparing the output signal 64 with the training data 59 corresponding to the Table I features. The computer algorithm sill select that coordinated output signal which have been stored in the training data 59. The computer algorithm will select that coordinated ouptut signal from the training data which most closely corresponds to the realtime signal 64. This activity is represented by

the data association block 70. The alarm condition 67 is identified by reason of a previously stored alarm activating signal contained within the computer memory 23. this activating signal triggers a display and audio alarm 71 which gives appropriate warning to the attending personnel.

In actual applications, the present alarm system was trained using an oil/water lung model. Fourteen critical events were created as identified in Table III. Each of these events was simulated 20 times to generate a strong statistical base of coordinated images representing each condition. After completing the training, the system was able to correctly identify 99.5% of the 14 different breathing circuit critical events which were recreated using the lung model.

The system received further training utilizing two mongrel dogs where 14 events were created, ten times each. The system was then tested on seven mongrel dogs having weights between 20 to 30 kilograms. 1,029 occurrences of 13 alarm conditions were created under controlled ventilation. In this test, the system correctly identified the cause 89.3% of the times. During spontaneous breathing, the system was able to detect 75.8% of ten separate alarm conditions that had been created as 236 repetitions.

The principal advantage of the neural network approach to alarm recognition is its ability to create the equivalent of hundreds of decision rules which previously were arbitrarily set by experts or other persons using ranges and threshold values as alarm signals. In contrast, the present system simply monitors the coordinated images or output signals generated by the neural network and classifies these

with respect to coordinated images generated in earlier training sessions. The system is not dependent upon assignment of arbitrary values, ranges or threshold levels. Instead, the present invention selects that critical event from the network's memory which is most similar to the coordinated image generated by the parallel input data.

It will be apparent to those skilled in the art that the foregoing examples are given as illustrations of the general inventive concepts, processes and devices. Disclosed examples are not, therefore, to be considered as limiting with respect to the claims which follow.

C L A I M S

1. A method for detecting and identifying alarm conditions in a mach setup, test animal or patient, or within an attached medical support or diagnostic device which generates output data suited for use in a neural network, said method comprising the steps of:

a) identifying at least one physiological function to be monitored with the medical support or diagnostic device;

b) identifying a plurality of separate but related features represented within the data to be generated by the medical support or diagnostic device during operation, said features providing indication of changing conditions with respect to the physiological feature to be monitored;

c) attaching the medical support or diagnostic device with means for generating and transmitting the data to the mach setup, test animal or patient and operating the device to generate data representing the plurality of identified related features;

d) transmitting and inputting generated data of the previous step representing the identified features to a computer system including input nodes of a neural network supported by the computer system, which neural network is capable of generating a single coordinated output signal for the combined input data;

e) identifying at least one alarm condition associated with the physiological function or medical support or diagnostic device which is to be programmed for detection;

f) empirically creating the alarm condition within the mach setup, clinical test animal or actual patient such that the input data being inputted to the input nodes of the neural network and representing the identified features produces a single coordinated output signal identifying the alarm condition;

g) storing and correlating the single coordinated output signal corresponding to the alarm condition and an associated alarm activating signal in computer memory for future recall such that recurrence of a similar single coordinated output signal automatically initiates the alarm signal to activate an alarm means which identifies the alarm condition.

2. A method as defined in Claim 1, comprising the additional steps of:

identifying a plurality of alarm conditions associated with the physiological function or medical support or diagnostic device;

empirically creating each respective alarm condition within the mach setup, clinical test animal or actual patient such that the respective corresponding input data being introduced to the input nodes of the neural network produces a corresponding coordinated output signal capable of identifying the alarm condition;

storing and correlating each coordinated output signal and an associated alarm activating signal in computer memory for future recall such that recurrence of a similar coordinated output signal will automatically initiate the alarm signal to activate an alarm means associated with the specific alarm condition.

3. A method as defined in Claim 1, comprising the additional step of providing an output node of the neural network for registering a nonalarm condition wherein no abnormal conditions are detected.

4. A method as defined in Claim 1, comprising the added step of incorporating an algorithm operable with respect to the neural network to identify which combination of features are most significant and provide weithting factors to the respective features to provide a single ouptut which serves as an indicator of an alarm condition.

5. A method as defined in Claim 1, further comprising the step of providing an alarm format which gives an audible warning of the occurrence of an alarm condition and identifies the nature of the specific condition to facilitate rapid corrective action.

6. A method as defined in Claim 1, wherein the alarm providing step includes identifying any component of the medical support or diagnostic device that is malfunctioning.

7. A method as defined in Claim 7, further comprising the step of graphically displaying the medical support or diagnostic device on a video screen with an identifier element designating the component which is identified by the neural network as a possible malfunctioning element.

8. A method as defined in Claim 1, wherein the method is applied as part of a process for detecting malfunctions or disorders occurring during mechanical ventilation of a patient, comprising the steps of:

a) selecting patient breathing as the physiological function to be monitored with medical

support or diagnostic devices;

b) identifying a plurality of features including air flow rate, pressure and carbon dioxide concentration within data generated by the medical support or diagnostic device which can be monitored in realtime condition;

c) attaching a mechanical ventilation device to the mach setup, test animal or patient and monitoring the breathing function to generate data;

d) transmitting the generated input data representing the breathing function to the computer system including input nodes of a neural network capable of generating a single coordinated output signal representing the combined input data;

e) identifying at least one alarm condition associated with the breathing function or mechanical ventilation device;

f) empirically creating the alarm condition within the ventilation device, mach setup, clinical test animal or actual patient such that the input data being inputted to the input nodes of the neural network and representing the identified features produces a coordinated image corresponding to the alarm condition;

g) associating the coordinated output signal representing the alarm condition and an alarm activating signal in computer memory for future recall such that recurrence of a similar coordinated output signal automatically initiates the alarm signal to activate an alarm means.

9. A method as defined in Claim 1, wherein the method is applied as part of a process for detecting malfunctions or disorders occurring during administration of anesthesia, comprising the steps of:

a) selecting the physiological function of patient breathing as the function to be monitored by

monitoring devices including sensors for airflow, air pressure and carbon dioxide concentration;

b) identifying a plurality of features within data generated by the monitoring devices while monitoring the referenced breathing function said features providing indication of changing conditions during administration of anesthesia;

c) attaching an anesthesia delivery device with monitoring sensors to the mach setup, test animal or patient and operating the delivery device while monitoring the breathing function to generate the input data;

d) transmitting and inputting the generated input data representing the breathing function to input nodes of a neural network capable of generating a single coordinated output signal from the combined input data;

e) identifying at least one alarm condition associated with the breathing function or anesthesia delivery device which is to be programmed for detection;

f) empirically creating the alarm condition within the mach setup, clinical test animal or actual patient such that the input data being fed to the input nodes of the neural network and representing the identified features produces a coordinated output signal corresponding to the alarm condition;

g) storing the coordinated output signal of the alarm condition and an associated alarm activating signal in computer memory for future recall such that recurrence of the same coordinated output signal automatically initiates the alarm signal to activate an alarm means.

10. A device as defined in Claim 21, wherein the neural network comprises a first level of input nodes, a second level of intermediate neurons

interconnected with the first level and a third level of output neurons interconnected with the second level to provide enhanced definition of boundary conditions for alarm conditions defined by output therefrom.

11. A method as defined in Claim 8, further comprising the step of extracting features from transducer signals which monitor patient breathing for data output in the form of pressure-volume curve, flow-volume curve and carbon dioxide concentration waveform.

12. A method as defined in Claim 9, wherein the step of identifying features comprises selecting (i) a first set of features that identify that breathing of the patient is not normal and (i) a second set of features applied upon detection of abnormal breathing that are used by the neural network to identify the cause for any abnormal change.

13. A method as defined in Claim 1, wherein the step of empirically creating the alarm condition is applied to the specific process of monitoring administration of anesthesia within an anesthesia delivery system, the creation of alarm conditions being developed by the steps of:

a) assembling a lung model;

b) attaching a ventilatory support or diagnostic system to the lung model;

c) attaching monitoring devices for measuring identified features as developed in the lung model;

d) simulating a malfunction and alarm condition within the anesthesia delivery system to generate the single coordinated output signal representing the malfunction and alarm condition;

e) storing the coordinated output signal corresponding to the malfunction and alarm condition

for future recall.

14. A method as defined in Claim 13, wherein the method is applied to detect tube and hose leaks and obstructions of the delivery system, hose disconnects and defects in valve operation.

15. A method as defined in Claim 1, wherein the step of inputting data to the input nodes includes the step of generating a single coordinated output signal in absolute form which represents a single reading of input data recorded into computer memory for future recall and comparison.

16. A method as defined in Claim 15, further comprising the step of classifying the absolute form of the coordinated output signals with respect to a breathing function as a coordinated output signal identifying an abnormal breath independent of all other breaths evaluated.

17. A method as defined in Claim 1, wherein the step of inputting data to the input nodes includes the step of generating a coordinated output signal which represents a comparative reading as opposed to an absolute reading of input data recorded into computer memory for future recall and comparison.

18. A method as defined in Claim 1, wherein the step of inputting data to the input nodes includes the step of generating a relative coordinated ouptut signal which represents a comparative series of realtime readings of input data.

19. A method as defined in Claim 17, wherein the step of inputting data includes the step of generating a coordinated output signal which

identifies a change in relative value of a monitored feature.

20. A method as defined in Claim 19, wherein the correlating step includes the step of correlating the comparative reading and resultant output signal with an alarm condition associated with relative changes in feature values as measured over a period of time.

21. A device for detecting and identifying abnormal conditions in a realtime environment within a patient's physiology through attached medical support and diagnostic devices, said device comprising:

a) a medical support or diagnostic device for attachment to a mach setup, test animal or patient and operable to monitor an identified physiological function;

b) sensors coupled to the support or diagnostic device for generating data representing a plurality of data features relating to the physiological function;

c) a neural network and supporting computer system coupled at neural input nodes to the sensors for receiving generated input data representing the identified features, said neural network being capable of generating a single coordinated output signal for the combined sensor input data;

d) identifying means within the computer system for identifying at least one stored alarm condition as a single coordinated output signal as is generated by a neural network corresponding to the alarm condition associated with the physiological function or medical support or diagnostic device which is to be detected;

e) detecting means within the neural network and supporting computer system for monitoring realtime data generated at the sensors and resultant single

coordinated output signals produced by the neural network which correspond to the stored alarm condition previously generated within a mach setup, clinical test animal or actual patient as part of an empirical training session;

f) alarm means coupled to the computer system for generating an associated alarm activating signal upon detection of a realtime single coordinated output signal similar to the stored output signal such that recurrence of the same coordinated output signal automatically initiates the alarm means.

22. A device as defined in Claim 21, wherein the stored alarm condition within the computer system comprises a statistically large number of single coordinated output signals which collectively define a single alarm condition to be detected.

23. A device as defined in Claim 22, further comprising a series of weighting factors which are applied and controlled by the computer system and an associated algorithm for a given alarm condition as part of an evaluation of input data at the neural network input nodes to establish relative importance to each feature corresponding to respective input nodes of the neural network with respect to the given alarm condition.

24. A device as defined in Claim 21, wherein the medical support or diagnostic device comprises an anesthesia delivery system and the sensors include sensors for monitoring air flow rate, air pressure, and carbon dioxide concentration during patient respiration.

25. A device as defined in Claim 24, wherein the alarm conditions include leaks and obstructions

within the delivery system and defective operation of valves.

26. A device as defined in Claim 24, wherein the plurality of data features include a first set of features that identify that breathing of a patient is not normal and a second set of features applied on detection of an abnormal breath to identify the cause of such abnormal response.

27. A method for detecting and identifying alarm conditions in a mach setup, test animal or patient, or within an attached medical support or diagnostic device which generates output data suited for use in a neural network, said method comprising the steps of :

a) identifying at least one physiological function to be monitored with the medical support or diagnostic device;

b) identifying a plurality of separate but related features represented within the data to be generated by the medical support or diagnostic device during operation, said features providing indication of changing conditions with respect to the physiological feature to be monitored;

c) attaching the medical support or diagnostic device with means for generating and transmitting the data to the mach setup, test animal or patient and operating the device to generate the data representing the plurality of identified related features;

d) transmitting and inputting generated data of the previous step representing the identified features to a computer system including input nodes of a neural network supported by the computer system, which neural network is capable of generating a single coordinated output signal for the combined input data;

e) identifying at least one alarm condition associated with the physiological function or medical support or diagnostic device which is to be programmed for detection;

f) comparing data output from the neural network in the form of single coordinated output signals previously created during a training sequence wherein at least one alarm condition was created to generate a statistical sampling of coordinated output signals representative of the alarm condition;

g) detecting which of the stored single coordinated output signals most nearly corresponds to realtime coordinated output signals;

h) identifying the alarm condition correlating to the detected stored single coordinated output signal; and

i) activating an alarm signalling device to alert medical attendants to the nature and cause of the alarm condition.

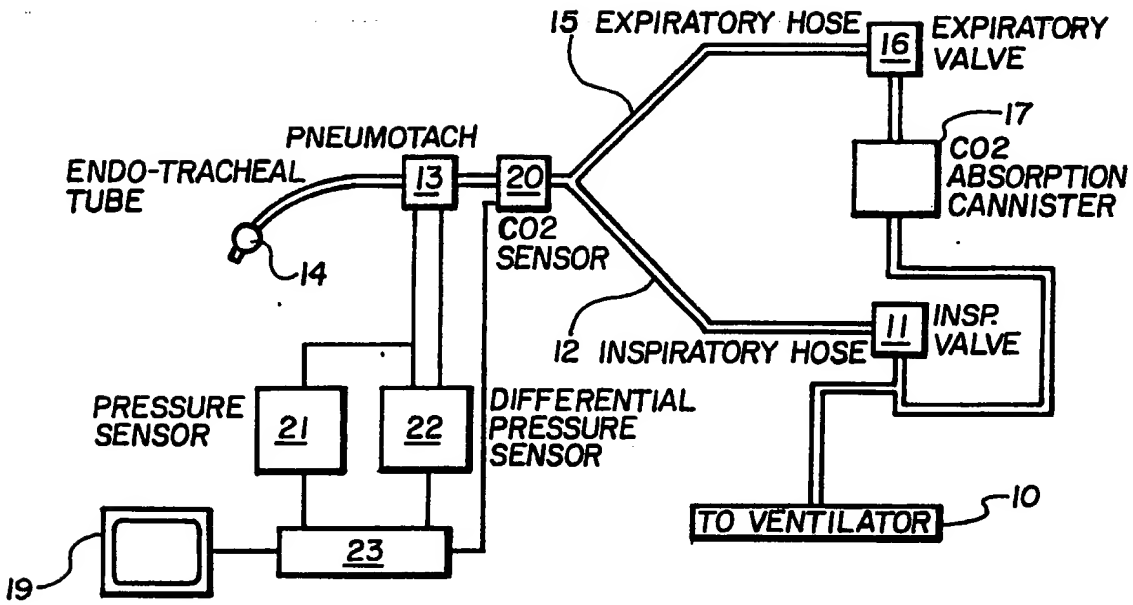


Fig. 1
(PRIOR ART)

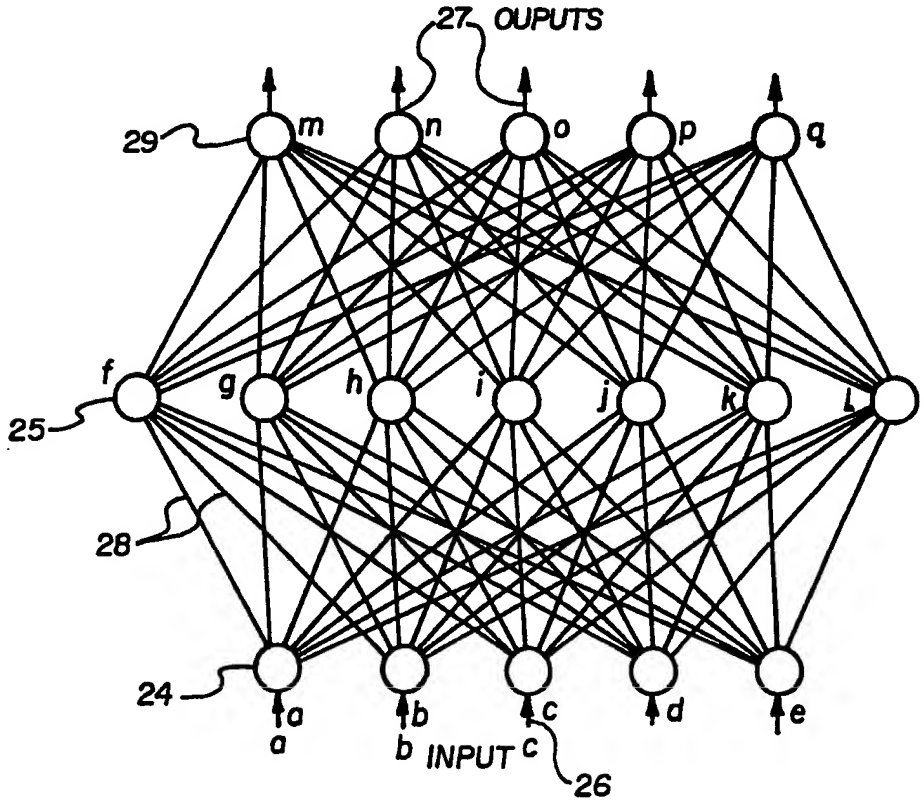


Fig. 2

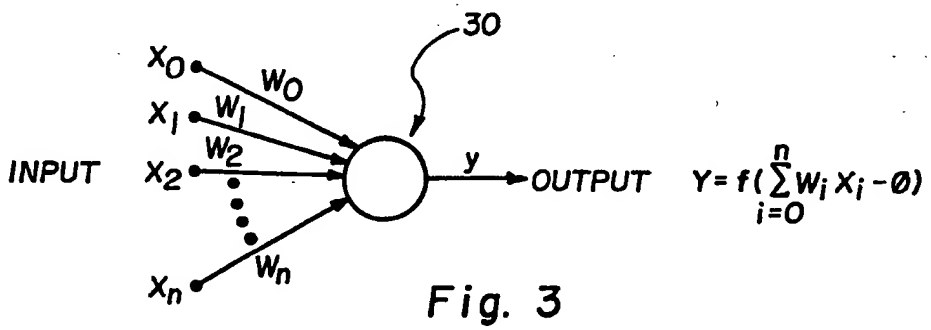


Fig. 3

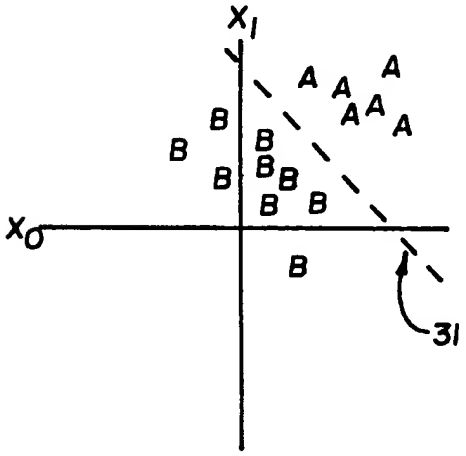


Fig. 4

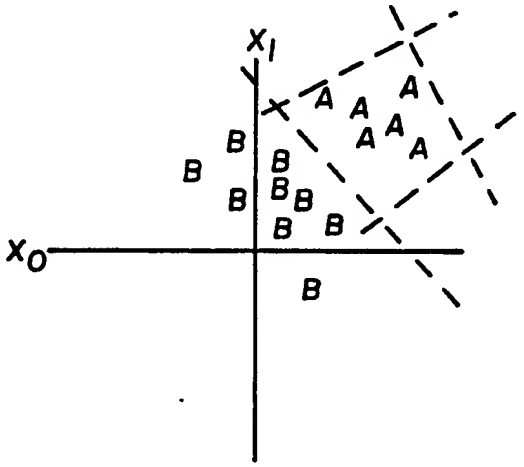


Fig. 5

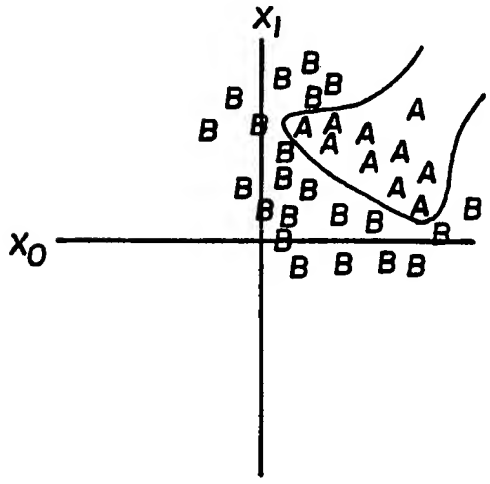


Fig. 6

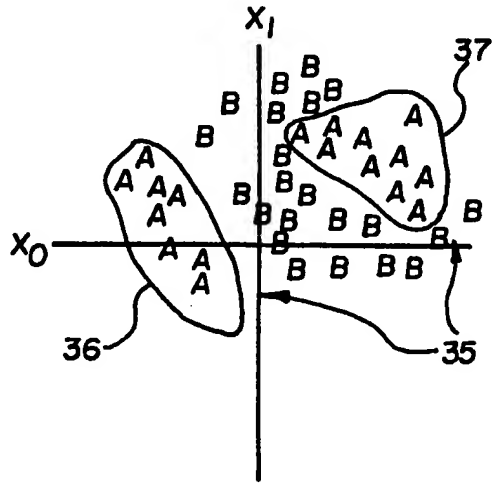


Fig. 7

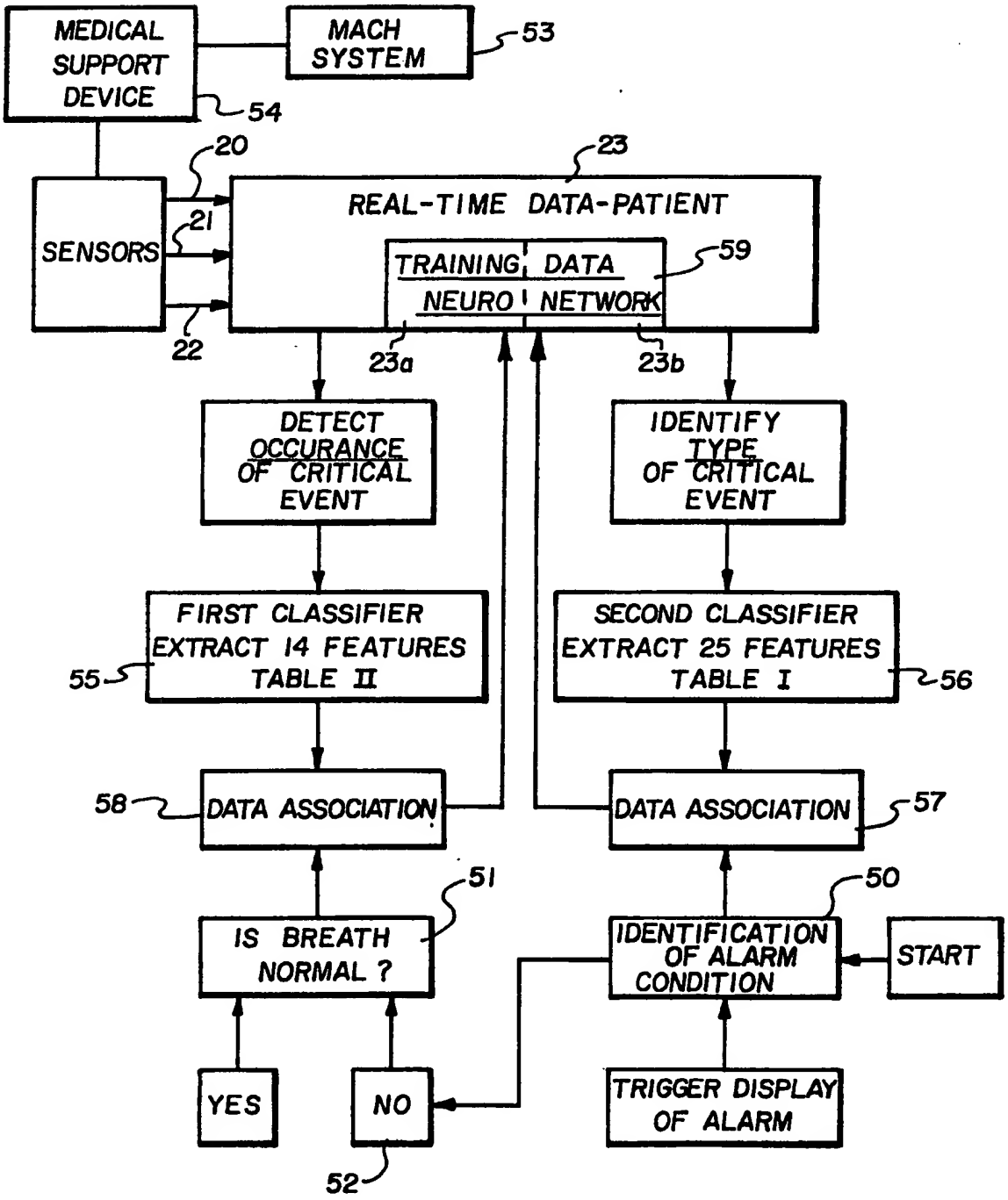
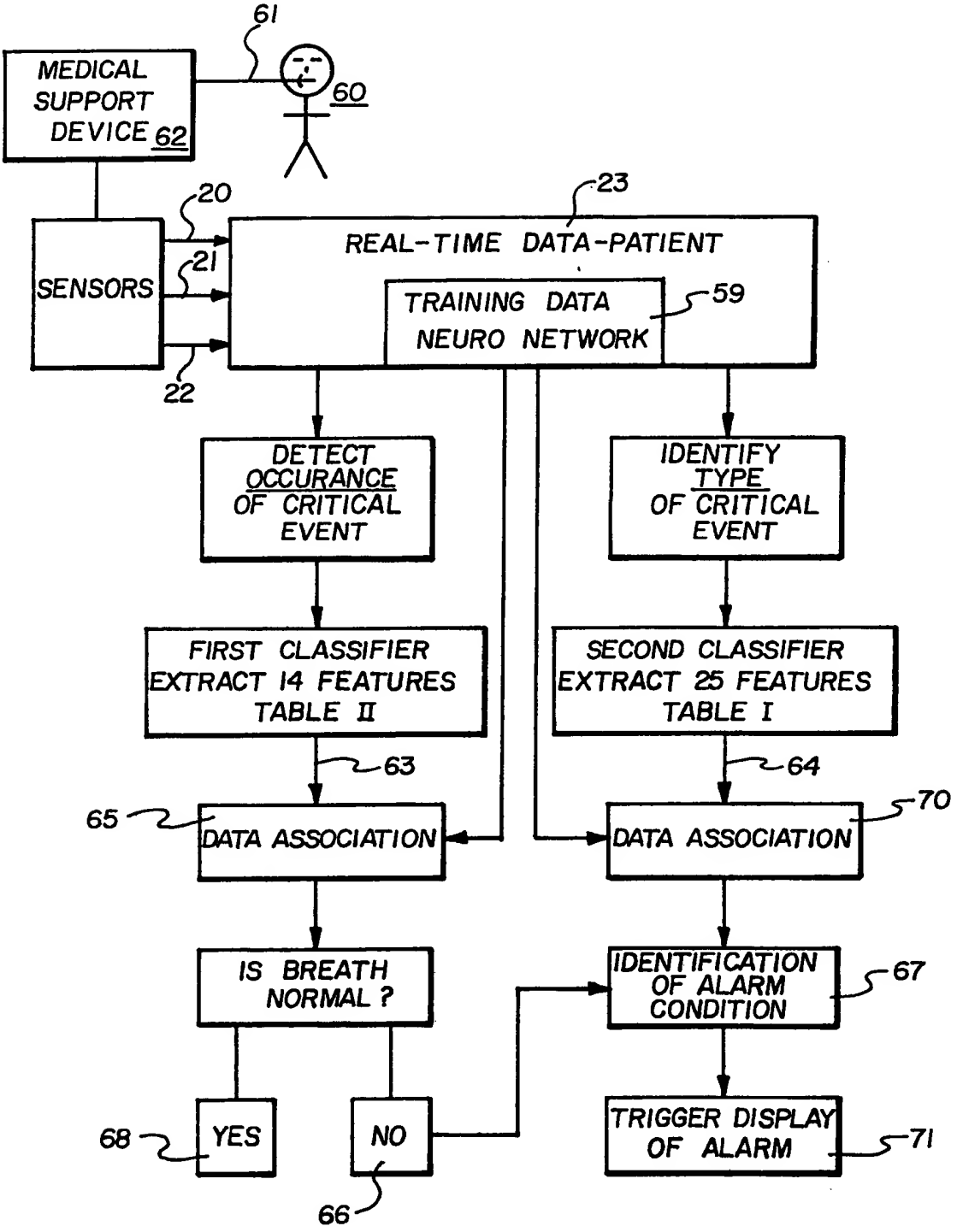

MEDICAL SUPPORT DEVICE
MACH SYSTEM
53
54
20
23
SENSORS
21
REAL-TIME DATA-PATIENT
TRAINING DATA
NEURO NETWORK
59
22
23a
23b
DETECT OCCURANCE OF CRITICAL EVENT
IDENTIFY TYPE OF CRITICAL EVENT
FIRST CLASSIFIER EXTRACT 14 FEATURES TABLE II
55
SECOND CLASSIFIER EXTRACT 25 FEATURES TABLE I
56
58
DATA ASSOCIATION
DATA ASSOCIATION
57
51
50
IS BREATH NORMAL ?
IDENTIFICATION OF ALARM CONDITION
START
YES
NO
TRIGGER DISPLAY OF ALARM
52

Fig. 8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TRAINING DATA NEURO NETWORK
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DETECT OCCURANCE OF CRITICAL EVENT
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64
65
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DATA ASSOCIATION
70
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IDENTIFICATION OF ALARM CONDITION
67
68
YES
NO
TRIGGER DISPLAY OF ALARM
71
66

Fig. 9

INTERNATIONAL SEARCH REPORT

International Application No PCT/US90/05250

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) 3

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5): A61B 5/08

U.S. CL: 128/716

II. FIELDS SEARCHED

Minimum Documentation Searched 4

Classification System	Classification Symbols
U.S.	128/204,21-204.23, 205.23, 202.22, 670, 671, 905, 716 604/65 364/513 382/15

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched 5

III. DOCUMENTS CONSIDERED TO BE RELEVANT 14

Category *	Citation of Document, 16 with indication, where appropriate, of the relevant passages 17	Relevant to Claim No. 18
A	IEEE ASSP MAGAZINE, issued April 1978 LIPPMANN, "An Introduction to computing with Neural Net", see pages 13-18	1-27
A	M.D. Computing, Vol. 5: (3), issued 1988, STUBBS "Neurocomputers," see page 9	1-27
A	British Journal of Anesthesiology issued 1985, KERR, "Warning Devices", see page 706	1-27

* Special categories of cited documents: 15

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search 2	Date of Mailing of this International Search Report 3
05 December 1990	27 FEB 1991
International Searching Authority 1	**Signature of Authorized Officer 11**
ISA/US	For K. Reichle

Form PCT/ISA/210 (second sheet) (May 1986)

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. [X] OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. [X] Claim numbers 1-27, because they relate to subject matter [1] not required to be searched by this Authority, namely:

(see attached sheet)

2. [ ] Claim numbers . because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [1], specifically:

3. [ ] Claim numbers_____, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. [ ] OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

This International Searching Authority found multiple inventions in this international applicat

1. [ ] As all required additional search fees were timely paid by the applicant, this international search repor of the international application.

2. [ ] As only some of the required additional search fees were timely paid by the applicant, this internationa those claims of the international application for which fees were paid, specifically claims:

3. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international se the invention first mentioned in the claims; it is covered by claim numbers:

4. [ ] As all searchable claims could be searched without effort justifying an additional fee, the International S invite payment of any additional fee.

Remark on Protest

[ ] The additional search fees were accompanied by applicant's protest.

[ ] No protest accompanied the payment of additional search fees.